

**UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF MISSISSIPPI
JACKSON DIVISION**

CYPRESS PHARMACEUTICALS, INC., and
HAWTHORN PHARMACEUTICALS, INC.

Plaintiffs,

v.

CRS MANAGEMENT, INC.,
PRACS INSTITUTE, LTD.,
GATEWAY MEDICAL RESEARCH, INC., and
BA RESEARCH INTERNATIONAL, L.P.,

Defendants.

Civil Action No. 3:10-cv-00691-TSL-FKB

**PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION
TO DEFENDANTS' MOTION TO DISMISS THE COMPLAINT**

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PRELIMINARY STATEMENT

Plaintiffs filed this lawsuit alleging that Defendants' tortious conduct resulted in injury and damages to Cypress, and its subsidiary, Hawthorn. Defendants moved to dismiss all of Plaintiffs' causes of action, and attempt to paint this case as nothing more than a dispute over performance under a contract. But Cypress has alleged Defendants' fraudulent conduct over a lengthy period of time, in violation of duties independent of the contract. More specifically, Plaintiffs allege that Defendants fraudulently concealed and misrepresented their employees' scientific fraud and their compliance with applicable standards. Plaintiffs also allege that Defendants were negligent in performing the study and in failing to train and supervise employees. Plaintiffs further allege that Defendants breached the fiduciary duty they owed to Cypress. Finally, Plaintiffs allege breach of contract (not challenged on Defendants' motion to dismiss), tortious breach of contract, and assert a claim for punitive damages.

In April 2008, Plaintiff Cypress Pharmaceuticals, Inc, acting on behalf of its wholly owned subsidiary, Hawthorn Pharmaceuticals, Inc.,¹ and relying on Defendants' purported expertise and experience, entrusted to Defendants an important clinical study. But Defendants' employees falsified scientific records relating to that clinical study, rendering Defendants' clinical study report, and the clinical trial itself, unreliable and worthless. Defendants knew or should have known of this misconduct, and knew that Cypress would rely on the report and the clinical study itself, in its new drug application to the U.S. Food and Drug Administration ("FDA").

No later than June 2009, Defendants knew that their employees had falsified scientific records over a multi-year period for multiple clients. Yet, even after reporting this scientific

¹ Unless otherwise noted, in this brief Plaintiffs Cypress Pharmaceuticals, Inc. and Hawthorn Pharmaceuticals, Inc., are referred to collectively as "Cypress" or "Plaintiffs."

fraud to the FDA in June 2009, Defendants affirmatively concealed the misconduct and their report from Cypress, although Cypress's application was still pending at FDA. Defendants wrongly concealed the misconduct from Cypress for a year after their report to FDA, while at the same time continuing to solicit business from Cypress.

Defendants' concealment continued even after FDA conducted an inspection of Defendants in May 2010 in connection with the very clinical study conducted by Defendants on behalf of Cypress. As a result of that inspection, FDA reported to Defendants that their employees had falsified records for multiple sponsors on multiple studies on at least 1,900 instances over a period of four years. And, even after FDA based its non-approval of Cypress's application on Defendants' scientific fraud, Defendants continued to conceal the operative facts from Cypress.

Plaintiffs were injured and damaged by Defendants' torts. These tortious actions form the crux of Plaintiffs' complaint. While Plaintiffs do assert a claim for breach of contract, that claim does not subsume Defendants' separate and independent torts.

As to Defendants' specific arguments in support of their motion to dismiss, Defendants contend that this Court lacks jurisdiction over them pursuant to Rule 12(b)(2), Fed. R. Civ. P. However, as shown below, this Court has jurisdiction over Defendants under all three prongs of Mississippi's long-arm statute, Miss. Code Ann. § 13-3-57. Alternatively, Defendants argue that Plaintiffs' tort claims should be dismissed pursuant to Rule 12(b)(6), Fed. R. Civ. P., under New Jersey's "economic loss rule." Yet Defendants fail to show that New Jersey law should apply to any claims, much less the tort claims, and do not argue that Plaintiffs' claims should be dismissed under the law of any other state. The 12(b)(6) motion should be denied for this reason

alone. Even assuming *arguendo* that New Jersey law applies, however, Plaintiffs have sufficiently pleaded their tort claims and the motion to dismiss should be denied.

BACKGROUND

Cypress Pharmaceuticals, Inc. and its wholly-owned subsidiary, Hawthorn Pharmaceuticals, Inc., are corporations organized and existing under the law of Mississippi and have their principal places of business in Madison, Mississippi. *See* Complaint [dkt. no. 1] (“Compl.”) ¶¶ 1, 7-8. Plaintiffs develop and market prescription drug products. *See id.* Before it can sell a new prescription drug product, a pharmaceutical company must first obtain approval from the FDA. *See id.* ¶¶ 2-3. In this case, Cypress was required to submit a new drug application to the FDA showing the results of a clinical trial demonstrating bioequivalence with one or more drugs already considered safe and efficacious. *See id.* ¶¶ 18-22, 28. Where it lacks the expertise or infrastructure to conduct such a clinical trial, a pharmaceutical company can rely on the expertise of a third-party contract research organization (“CRO”) that specializes in conducting clinical trials to perform the study and report its results. *See id.* ¶¶ 14, 18-22, 28. Defendants CRS Management, Inc. (“CRS”) d/b/a Cetero Research; PRACS Institute, Ltd. (“PRACS”) d/b/a Cetero Research; Gateway Medical Research, Inc. (“Gateway”) d/b/a Cetero Research; and BA Research International, L.P. (“BA Research”) d/b/a Cetero Research are a family of CROs (collectively, “Cetero”) engaged in the business of conducting clinical trials and bioanalytical studies for pharmaceutical companies. *See id.* ¶¶ 9-14.

Starting in 2006 and continuing at least through 2009, Cypress was contacted on numerous occasions in Mississippi by Defendants who sought to perform clinical trials for Cypress. *See* Declaration of Robert Lewis, dated March 2, 2011 (“Lewis Decl.”) ¶¶ 2-4, 12, 14, Exs. 1-5, 8, 10-11, 16-18. Defendants sent budget proposals to Cypress, and had numerous follow-up communications gauging Cypress’s interest in doing business with Defendants. *See*

id. In 2008, following multiple communications with Cypress, Defendants entered into several separate agreements to conduct clinical trials on behalf of Cypress. On April 30, 2008, Cypress executed an agreement for clinical trial S08-0179 for a combination drug product for the treatment of cough and cold symptoms (“the S08-0179 Study” and “the Study Agreement”) that is at issue in this case. *See* Compl. ¶¶ 19-22; Defendants’ Motion to Dismiss Plaintiff’s Complaint, Ex. A [dkt. no. 12-1]; Lewis Decl. ¶ 5. On June 20, 2008, Cypress executed three more Single Study Agreements, and in July 2008, it engaged Cetero to perform yet another study. *See* Lewis Decl., Exs. 9, 13-15.

Among other things, the S08-0179 Study Agreement obligated Cypress to “provide, without any charge to CETERO or a CETERO affiliate, all drugs or test articles to be studied under this Agreement and/or the Protocol.” Study Agreement § 4.1; Compl. ¶ 17(a). In performing these contractual obligations, Cypress shipped reference drug materials to be used in the study to Cetero from its Mississippi facility. Lewis Decl. ¶ 7; Compl. ¶ 17(a). The Study Agreement also obligated Cetero to perform the clinical study in accordance with accepted standards of “Good Clinical Practice and Good Laboratory Practice.” Compl. ¶ 20(b). Upon completion of the study in the fall of 2008, Defendants delivered at least one copy of its study report to Cypress at Cypress’s Mississippi facility. Compl. ¶¶ 17(a), 27; Declaration of Laura Sheppard, dated Feb. 3, 2011, ¶ 5 [dkt. no. 12-4]. That report contained multiple certifications of compliance with applicable standards, including a certification that:

Cetero had complied with both [Good Clinical Practices and Good Laboratory Practices], that compliance with these standards and with Cetero’s own [Standard Operating Procedures] had been reviewed for and met Quality Assurance standards, and that Cetero had complied with other regulatory and statutory requirements.

Compl. ¶ 27.

In connection with the S08-0179 Study, Defendants delivered five invoices to Cypress's Mississippi facility, addressed to Mr. Robert Lewis, Cypress's Chief Science Officer, between May and November 2008. *See* Lewis Decl. ¶ 9, Ex. 7. Cypress paid Defendants from the Mississippi facility using checks drawn on Cypress's bank account at the Jackson, Mississippi location of Trustmark National Bank. *See* Lewis Decl. ¶ 11, Ex. 7.

At least as early as June 2009, Defendants knew that laboratory technicians at the Houston bio-analytical facility had falsified certain data, including data affecting the quality, integrity, and reliability of Study S08-0179. Compl. ¶¶ 46(d), 49, 52. Defendants conducted an internal investigation and reported the results to the FDA in June 2009. *See id.* Although Defendants communicated with Cypress on numerous occasions after making this discovery, *see id.* ¶ 34, and sought to obtain further business from Cypress, they did not disclose the data falsification or their report to the FDA to Cypress. *See id.* ¶¶ 54, 61. Nor did they inform Cypress that the report for Study S08-0179 and their certifications in that report were compromised and unreliable.

Even after the discovery of the data falsification, Defendants continued to seek business from Cypress. For example, in July, September, and December 2009, Defendants sent emails to Mr. Lewis seeking to perform several clinical trials that Cypress wanted to conduct (even though, as set out below, Defendants were aware by this time of the scientific fraud by its employees). Lewis Decl. ¶ 14; Exs. 17-18. Defendants also offered to visit Cypress's Mississippi facility, although no visit occurred due to Cypress company policy. Lewis Decl. ¶ 14; Ex. 17.

In May 2010, the FDA conducted an inspection of Cetero's Houston facility. It was only after this inspection and the FDA inspectors issued their report of findings that Cypress was

informed of the data falsification by Cetero's employees. *See* Compl. ¶¶ 54, 61. Even then, Cetero affirmatively concealed FDA's inspection report and the operative facts from Cypress for two months, finally disclosing the report only after forcing Cypress to enter into a confidentiality agreement. *See id.* ¶¶ 40-46. Ultimately, Cypress obtained a copy of FDA's report pursuant to a Freedom of Information Act request. The FDA's inspection report disclosed that Cetero had falsified records "in at least 1900 instances over the period April 15, 2005 to June 30, 2009," affecting "multiple studies for multiple sponsors." *Id.* ¶ 50; *see id.* ¶¶ 47-50.

As a result of the data falsification by Cetero, the FDA rejected Cypress's new drug applications, of which the S08-0179 Study and Defendants' clinical study report were an integral part. *See* Compl. ¶¶ 55-62. Had Cetero disclosed that the study was compromised in June 2009 when it sent its report to the FDA, Cypress would have engaged another CRO to conduct new clinical trials. *See id.* ¶¶ 58-60. Because Cetero concealed the data falsifications and affirmatively communicated the false impression that everything was fine—when in fact disaster had struck—Cypress was deprived of the chance to fix the problem for approximately one year. As a result, Cypress was injured and damaged, suffering lost profits and lost market share. And, of course, it lost the value of the study itself, and had to pay for a replacement study. *See id.* ¶ 62.

ARGUMENT

I. DEFENDANTS ARE SUBJECT TO THE JURISDICTION OF MISSISSIPPI COURTS UNDER ALL THREE PRONGS OF THE LONG-ARM STATUTE

Cypress has more than alleged a sufficient factual basis for the exercise of personal jurisdiction under all three prongs of the Mississippi long-arm statute. That statute provides that a corporation or limited partnership not qualified to do business in Mississippi may be subjected to personal jurisdiction if it: (a) "make[s] a contract with a resident of this state to be performed

in whole or in part by any party in this state”; (b) “commit[s] a tort in whole or in part in this state against a resident ... of this state”; or (c) “do[es] any business or performs any character of work or service in this state.” Miss. Code Ann. § 13-3-57. Jurisdiction exists over Defendants under each of the prongs of the long-arm statute. Specifically:

- (1) The Court has jurisdiction over CRS under the first, or “contract prong.” CRS entered into the Study Agreement with Cypress, a resident of this state, and the agreement was performed at least in part in this state, as Cypress’s contractual obligations were performed in Mississippi, and CRS’s invoices and study report were delivered to Cypress in Mississippi.
- (2) The Court has jurisdiction over all Defendants under the “tort prong” of the long-arm statute. Cypress has alleged that each tort was committed in part in Mississippi, and in particular, has alleged that injury to Cypress took place in Mississippi.
- (3) The Court has jurisdiction over all Defendants under the “doing business prong” of the statute. Defendants entered into several contracts with Cypress, sent numerous emails and made numerous phone calls to Cypress in this state for the purpose of soliciting business and presenting Cypress with budget proposals for clinical studies on multiple occasions. This conduct is more than sufficient to constitute doing business within the meaning of the long-arm statute. Indeed, Defendants continued to solicit business from Cypress in Mississippi even after they reported the data falsification to FDA and knew that the study they had conducted for Cypress was worthless.

Where “the Court does not rely on an evidentiary hearing but instead decides the motion on the pleadings and exhibits on file, the party urging jurisdiction is only required to present a *prima facie* case of personal jurisdiction.” *Aultman, Tyner & Ruffin, Ltd. v. Capital Rubber & Specialty Co.*, No. 2:10cv223KS-MTP, 2011 WL 213471, at *4 (S.D. Miss. Jan. 21, 2011) (citing *Brown v. Flowers Indus., Inc.*, 688 F.2d 328, 332 (5th Cir. 1982)). Further,

[t]he allegations of the complaint except insofar as controverted by opposing affidavits must be taken as true, and all conflicts in the facts must be resolved in favor of the plaintiffs for purposes of determining whether a *prima facie* case for personal jurisdiction has been established.

Id. at *5 (quoting *Thompson v. Chrysler Motors Corp.*, 755 F.2d 1162, 1165 (5th Cir. 1983)).

While Defendants have submitted affidavits, nothing in the affidavits controverts the allegations of the complaint. The allegations of the complaint, combined with the exhibits submitted by Cypress in connection with this memorandum of law and supporting declaration, are more than adequate to form a *prima facie* case for personal jurisdiction over all Defendants.

A. Because All Of Cypress's Contractual Obligations Were Performed In Mississippi, Personal Jurisdiction May Be Exercised Over Defendant CRS Under The Contract Prong Of The Long-Arm Statute

Under the contract prong of the long-arm statute, personal jurisdiction over a contracting party may be exercised even “when only a single contract exists” between the plaintiff and defendant. *Sorrells v. R & R Custom Coach Works, Inc.*, 636 So. 2d 668, 671 (Miss. 1994) (citing *Kaydee Metal Prods. Corp. v. Sintex Mach. Tool Mfg. Corp.*, 342 F. Supp. 902, 906 (N.D. Miss. 1972)). One of the parties must also be a Mississippi resident. Here, both Plaintiffs are residents of this state. *See* Compl. ¶¶ 7-8. The only other jurisdictional requirement is that some part of the contract be performed in Mississippi. *See* Miss. Code Ann. § 13-3-57. The Complaint alleges the contract was performed in part in Mississippi, “including the delivery of clinical supplies from Cypress to Cetero, the delivery of clinical study reports to Cypress in Mississippi, and payment by Cypress to Cetero.” Compl. ¶ 17(a). The Study Agreement lays out Cypress's obligation to “provide, without any charge to CETERO or a CETERO affiliate, all drugs or test articles to be studied under this Agreement and/or the Protocol,” Study Agreement § 4.1, and Cypress sent test products for the reference drug to be used in the S08-0179 study to Cetero from its Madison, Mississippi facility. Lewis Decl. ¶ 7. Mississippi District Courts have recognized the sufficiency of comparable contract provisions for purposes of establishing personal jurisdiction under the contract prong of the Mississippi long-arm statute. *See Genesis Press, Inc. v. Carol Publ'g. Grp., Inc.*, No. 1:99CV311-B-D, 2000 WL 33907680, at *2 (N.D.

Miss. Mar. 30, 2000) (finding the contract prong fulfilled because “part of the contract required the plaintiff to send its books from Mississippi”).

Defendants acknowledge that they delivered the S08-0179 study reports to Cypress in Mississippi. Defs. Br. 7; Sheppard Decl. ¶ 5. And Cypress received Defendants’ invoices at its offices in Mississippi and paid those invoices from Mississippi through funds drawn on the Jackson, Mississippi branch of Trustmark National Bank. Lewis Decl. ¶ 11; Ex. 7 (invoices and check history report). Such contractual payment, standing alone, has also been found by this Court to meet the requirements of the contract prong. *See Madami Int’l, LLC v. Dinli Metal Indus. Co.*, 276 F. Supp. 2d 586, 588 (S.D. Miss. 2002) (part performance of contract in Mississippi found from “uncontroverted evidence, via [affidavit], that Dinli sent invoices for payment ... to plaintiffs’ address in Jackson, Mississippi and that plaintiffs made payment back to Dinli from their Jackson, Mississippi address.”); *see also Charles v. Al-Anssi*, No. 1:06CV556-LG-RHW, 2007 WL 843843, at *4 (S.D. Miss. Mar. 19, 2007) (contract found to be partially performed in Mississippi when equipment delivered to Mississippi and payments made for equipment from Mississippi).

Despite the clear language of the long-arm statute requiring only partial performance of the contract “by *any party* in this state,” Defendants wrongly assume that only the actions of Defendants are relevant. Thus, Defendants’ rejoinder to Cypress’ allegation that delivery of clinical trial supplies by Cypress establishes jurisdiction is that “Defendant Gateway received the clinical supplies in Missouri ... and no representative ever went to Mississippi.” Defs. Br. 7 (emphasis removed). This argument is simply irrelevant, as Cypress performed its contractual duties in Mississippi.

Defendants also miss the point in arguing that “[m]erely contracting with a resident of the forum state is insufficient to subject the nonresident Defendants to personal jurisdiction.” Defs. Br. 7 (citing *Colwell Realty Invs., Inc. v. Triple T Inns of Ariz., Inc.*, 785 F.2d 1330, 1334 (5th Cir. 1986)).² Plaintiffs have not alleged merely contracting with a resident of Mississippi. Rather, the Complaint clearly spells out that partial *performance* of the contract occurred in Mississippi.

Beyond the performance of a contract, in conducting its due process analysis, “the Court must ‘look to the factors of prior negotiations, contemplated future consequences, terms of the contract, and the parties’ actual course of dealing to determine whether [the nonresident defendant] purposefully established minimum contacts with the forum.’” *Colwell Realty*, 785 F.2d at 1334 (quoting *Stuart v. Spaderman*, 772 F.2d 1185, 1193 (5th Cir. 1985)). Each of these factors favors the exercise of personal jurisdiction. Cypress negotiated the contractual terms and communicated with Defendants concerning the details of the study protocol from Mississippi. Lewis Decl. ¶ 4, Exs. 3-5. The contractual terms required Cypress to provide clinical trial supplies, and Cypress sent test products for the study to Defendants from Mississippi. Lewis Decl. ¶ 7. The parties’ course of dealing included invoices delivered to Mississippi, payment

² In *Colwell Realty*, the plaintiff sought to exercise jurisdiction under Texas’s long-arm statute, although there was no allegation of any performance of any contract in Texas. The plaintiffs in that case also had no connection with Texas during the negotiation and execution of the relevant limited partnership agreement. 785 F.2d at 1331. Only after the agreement was executed was a new corporation created that was incorporated in Texas, and the defendants were asked to consent to the substitution of the Texas corporation for the original party as a new limited partner. *Id.* Thus, the court held only that plaintiffs’ “state of incorporation, by itself, is insufficient to confer jurisdiction over the nonresident [defendant].” *Id.* at 1334.

from Mississippi, and the delivery of the finished product—the clinical study report—to Plaintiffs in Mississippi.³ Lewis Decl. ¶¶ 7, 9-11; Sheppard Decl. ¶ 5.

This Court therefore has jurisdiction over CRS under the contract prong of the long-arm statute.

B. The Requirements Of The Tort Prong Of The Long-Arm Statute Are Met By Cypress's Reliance In Mississippi On Defendants' Misrepresentations And Omissions

“Under the tort prong of the Mississippi long-arm statute, personal jurisdiction is proper if any element of the tort (or any part of any element) takes place in Mississippi.” *Paz v. Brush Engineered Materials, Inc.*, 445 F.3d 809, 812 (5th Cir. 2006) (quoting *Allred v. Moore & Peterson*, 117 F.3d 278, 282 (5th Cir. 1997)). At least one element of each tort alleged in the Complaint occurred in Mississippi. Accordingly, exercise of personal jurisdiction over all Defendants is appropriate.

Defendants make much of the doctrine that the actual injury from the tort must occur in Mississippi, and not simply the “consequences stemming from the actual injury.” Defs. Br. 8 (quoting *Jobe v. ATR Mktg., Inc.*, 87 F.3d 751, 753 (5th Cir. 1996)). But Defendants badly misconstrue the allegations of the Complaint in arguing that the only injuries alleged are “the alleged falsification of data, alleged concealment of such falsification and the alleged failure to train and adequately supervise employees.” *Id.* at 9 (citing Compl. ¶¶ 69, 75, 80, 87, 96). Yet again, Defendants improperly focus only on their own conduct.

³ Each of these factors distinguish the instant case from the circumstances of *Peterson v. Test Int'l, E.C.*, 904 F. Supp. 574 (S.D. Miss. 1995), cited by Defendants. See Defs. Br. 8. No portion of the employment contract in *Peterson* was alleged to have taken place in Mississippi. *Id.* at 576-77. The plaintiff's only argument in that case, that the first leg of his self-funded travel from Mississippi to New Orleans or Houston en route to the job site in Algeria fell “within the scope of his employment,” was rejected by the court. *Id.* By contrast, Cypress performed its obligations as spelled out by the contract entirely within Mississippi.

Injury is defined in Mississippi law not as the conduct of the defendant, but as the “actual invasion of a legally protected interest.” *Allred*, 117 F.3d at 282. The Complaint alleges not only the sustained misconduct of the Defendants in falsifying data and concealing the falsifications and the results of the falsifications from Cypress, but also, and most importantly for the jurisdictional analysis, Cypress’s detrimental reliance on Defendants’ misrepresentations and omissions. Cypress’s detrimental reliance occurred in Mississippi, and this alone is enough to establish personal jurisdiction under the Mississippi long-arm statute. *See Koegel v. Baugur Grp., HF*, 238 F. App’x 5, 6 (5th Cir. 2007) (actionable injury for purposes of tort prong of long-arm statute may consist in “the plaintiffs’-appellants’ change of position ... in justifiable reliance on the representations that [defendant] made”).

Cypress’s detrimental reliance on Defendants’ misrepresentations is repeatedly alleged throughout the Complaint. *See* Compl. ¶¶ 6, 17(b), 29-30, 33, 35, 58-60, 69-71, 75-76, 80-81, 91-92. Most significantly, Cypress was unaware of the scientific fraud by Defendants’ employees and the impact of that fraud on the integrity and reliability of Study S08-0179, and therefore continued to rely on the integrity of the study. Cypress relied on and reposed trust in Defendants’ certifications that they had complied with applicable standards. *See id.* ¶¶ 34, 52-54. Such reliance is an important element of Plaintiffs’ tort claims. *See Mabus v. St. James Episcopal Church*, 13 So. 3d 260, 264 (Miss. 2009) (fraudulent concealment claim requires hearer’s ignorance of the falsity of defendant’s representation and hearer’s justifiable reliance on its truth); *Schmidt v. Catholic Diocese of Biloxi*, 18 So. 3d 814, 831 (Miss. 2009) (same for fraudulent misrepresentation); *Mladineo v. Schmidt*, -- So. 3d --, 2010 WL 4242620, at *10 (Miss. Oct. 28, 2010) (negligent misrepresentation claim requires that “that the plaintiff reasonably relied upon the misrepresentation or omission”). Similarly, a claim for breach of

fiduciary duty requires the existence of a fiduciary relationship, which arises “where the parties repose trust in one another,” *Holland v. Peoples Bank & Trust Co.*, 3 So. 3d 94, 101 (Miss. 2008) (internal quotation marks and citations omitted), and which Cypress has alleged, *see* Compl.

¶ 91. Because both Cypress’s detrimental reliance on Defendants’ misrepresentations and its reposing of trust in Defendants necessarily occurred in Madison, Mississippi, Cypress has adequately alleged that one or more elements of the torts alleged occurred in Mississippi, thus satisfying the tort prong of the long-arm statute.

This Court has found jurisdiction based on the detrimental reliance by plaintiffs within this state. In one case, jurisdiction was exercised over defendants alleged to have participated in an illegal tax-avoidance trust because “the actual invasion of [plaintiffs’] legal right occurred in Mississippi when they were induced to invest in the trust in reliance on the opinion letter directed by [defendants] to them in Mississippi.” *Vig v. Indianapolis Life Ins. Co.*, 384 F. Supp. 2d 975, 979 (S.D. Miss. 2005) (Lee, J.). Jurisdiction was found despite the fact that the opinion letter “was drafted in Pennsylvania for [defendants’] client in California,” given that defendants “clearly knew and intended that the letter would be sent to [plaintiff] in Mississippi.” *Id.* at 978, 980. In another case involving an allegation of fraudulent concealment, this Court concluded that misleading sales figures provided to a Mississippi corporation were sufficient to support a finding that “the torts in question were allegedly committed at least in part in this state against a resident ... of this state.” *Morrone Co. v. Barbour*, 241 F. Supp. 2d 683, 687 (S.D. Miss. 2002) (Lee, J.). Numerous other courts have made similar findings. *See, e.g., Elwood v. Cobra Collection Agency*, No. 2:06cv91-KS-JMR, 2006 WL 3694594, at *2 (S.D. Miss. Dec. 14, 2006) (telephone conversations violating the Fair Debt Collection Practices Act that transpired while plaintiff was physically located within Mississippi conferred jurisdiction over out-of-state

defendant); *Cox v. Foundation Surgery Ctr. of San Antonio, L.L.P.*, No. 1:06CV97-D-D, 2006 WL 3246390, at *2 (N.D. Miss. Nov. 8, 2006) (single telephone call by defendant from Texas to Mississippi making fraudulent misrepresentation sufficient to establish *prima facie* case of personal jurisdiction under tort prong); *Huggins v. Aon Corp.*, No. 1:05CV157-D-D, 2006 WL 709787, at *2-3 (N.D. Miss. Mar. 16, 2006) (omission leading to plaintiff's detrimental reliance in Mississippi sufficient to establish personal jurisdiction). Cypress's detrimental reliance is comparable to the allegations in each of these cases and creates a clear *prima facie* demonstration of personal jurisdiction under the tort prong of the long-arm statute.

C. Defendants' Entry Into Multiple Contracts With Cypress, Delivery Of Budget Proposals, And Sales Pitches To Cypress In Mississippi Are Sufficient To Exercise Personal Jurisdiction Over Defendants Under The "Doing Business" Prong Of The Long-Arm Statute

The "doing business" prong of the long-arm statute requires only a *prima facie* showing that Defendants have done "any business or perform[ed] any character of work or service in this state." Miss. Code Ann. § 13-3-57 (emphases added). This question turns on whether Defendants performed "various acts here for the purpose of realizing a pecuniary benefit or otherwise accomplishing an object." *Coats v. Penrod Drilling Corp.*, 5 F.3d 877, 882 (5th Cir. 1993) (quoting *McDaniel v. Ritter*, 556 So. 2d 303, 309 (Miss. 1989)).⁴ The Court need not assess whether Defendants' "contacts with Mississippi were 'continuing' and 'substantial' or 'continuous' and 'systematic.'" *Internet Doorway, Inc. v. Parks*, 138 F. Supp. 2d 773, 779 (S.D. Miss. 2001). Instead, "even a single contact can support specific jurisdiction." *Id.* In *Internet*

⁴ Defendants misstate the law in claiming that the cause of action must somehow be connected with the business done in Mississippi. See Defs. Br. at 11 (quoting *Cycles, Ltd. v. W.J. Digby, Inc.*, 889 F.2d 612, 620 (5th Cir. 1990)). The long-arm statute, as amended in 1991, "does not require any nexus between the nonresident's Mississippi business and the injury." *Gross v. Chevrolet Country, Inc.*, 655 So. 2d 873, 878 (Miss. 1995); see also *Wright v. Davis*, No. 3:08CV97-DPJ-JCS, 2008 WL 4999165, at *2 (S.D. Miss. Nov. 19, 2008).

Doorway, for example, a single email sent by the defendant constituted doing business and subjected it to the jurisdiction of the court. *Id.* Defendants entered into several contractual arrangements with Cypress, to be at least partially performed in this state. Defendants directed multiple reports and invoices, as well as numerous emails and other communications to Cypress, in Mississippi, over the course of several years as they solicited, transacted, and consummated business with Cypress. This conduct easily fulfills the requirements of this final prong of the long-arm statute.

Defendants' solicitations to Cypress began as early as November 2006, when a Cetero "Business Development Associate" emailed a budget proposal to Cypress's Chief Scientific Officer Rob Lewis regarding an upcoming bioequivalence study. *See* Lewis Decl. ¶ 3, Ex. 1. In 2008, Cypress engaged Defendants to conduct multiple studies, including Study S08-0179, the subject of the instant litigation. *See* Lewis Decl. ¶¶ 5, 12, 13 (listing studies).

Defendants' solicitations continued in 2009, even after they had reported their employees' data fraud, and knew that the S08-0179 Study they had conducted on behalf of Cypress was worthless. In 2009, another Cetero business development employee sent a series of emails for the purpose of selling clinical trial services to Cypress. *See* Lewis Decl. ¶ 14, Exs. 16-18. That employee also proposed to visit Mr. Lewis at Cypress's facility in Mississippi. *Id.* That visit did not occur because of Cypress's policy of not allowing visitors. *Id.* These multiple acts directed toward Mississippi with the "purpose of realizing a pecuniary benefit," *Coats*, 5 F.3d at 882, easily meet the requirements of the "doing business" prong, and create an additional basis for the exercise of personal jurisdiction over all Defendants. *See also Internet Doorway*, 138 F. Supp. 2d at 775-76 (solicitation of business by email constitutes "'doing business' within the contemplation of the Mississippi long-arm statute.").

D. Cypress's Allegation Of Intentional Torts Committed By Defendants Is Sufficient To Satisfy Due Process Requirements For The Exercise Of Jurisdiction Over Defendants With Respect To All Claims

The commission of fraud-based torts in Mississippi is sufficient to satisfy the due process requirements of the Constitution, which requires that the nonresident have “purposefully availed” itself of the “benefits and protections” of Mississippi by establishing “minimum contacts” with Mississippi such that the Defendants could “reasonably anticipate being haled into court in the forum state,” and that the “exercise of jurisdiction does not offend ‘traditional notions of fair play and substantial justice.’” *Wien Air Alaska, Inc. v. Brandt*, 195 F.3d 208, 211 (5th Cir. 1999) (quoting *Holt Oil & Gas Corp. v. Harvey*, 801 F.2d 773, 777 (5th Cir. 1986)).

Even a “single act” by Defendants directed toward Cypress that gives rise to a cause of action supports a finding of minimum contacts. *Id.* at 211-12 (citing *Calder v. Jones*, 465 U.S. 783, 788-89 (1984)). Here, the Complaint alleges misrepresentations and omissions by Defendants that were directed toward Cypress in Mississippi. *See* Compl. ¶¶ 17(b), 52-54, 64-65, 69, 79-80, 95-96. Further, “[w]hen the actual content of communications with a forum gives rise to intentional tort causes of action, this alone constitutes purposeful availment.” *Wien Air*, 195 F.3d at 213. Here, as in *Wien Air*, Cypress has alleged that the Defendants’ communications toward Cypress in Mississippi gives rise to the intentional tort of fraudulent concealment, among other claims, sufficient to confer jurisdiction. *Id.* at 211; Compl. ¶¶ 63-71. Cypress has accordingly established a *prima facie* case of minimum contacts over Defendants not only with respect to the fraud-based tort claims, but all other claims as well (including negligence and punitive damages), which arise out of the same series of events. *See Cantex Energy Corp. v. World Stock Exch., LLC*, No. SA-09-CA-0218-XR, 2009 WL 2407959, at *4 n.7 (W.D. Tex. Aug. 4, 2009) (“due process permits a court to assert jurisdiction over all related claims that arise out of a defendant’s minimum contacts with the forum.” (citing *Sutton v.*

Advanced Aquaculture Sys., Inc., 621 F. Supp. 2d. 435 (W.D. Tex. 2007)); *see also Wien Air*, 195 F.3d at 215 (finding fraud-based minimum contacts established by plaintiff over defendant sufficient to establish jurisdiction “with respect to its claims for fraud, fraudulent inducement, breach of contract and breach of fiduciary duty.”).

“Once a plaintiff has established minimum contacts, the burden shifts to the defendant to show the assertion of jurisdiction would be unfair,” and “the defendant must make a compelling case against it.” *Wien Air*, 195 F.3d at 315 (citations omitted). Further, if “a cause of action for fraud committed against a resident of the forum is directly related to the tortious activities that give rise to personal jurisdiction, an exercise of jurisdiction likely comports with the due process clause, given the obvious interests of the plaintiff and the forum state.” *Id.* (citing *D.J. Invs., Inc. v. Metzeler Motorcycle Tire Agent Gregg, Inc.*, 754 F.2d 542, 548 (5th Cir. 1985)). The assertion of jurisdiction here is plainly fair, as the only conceivable burden on Defendants—that it must litigate in Mississippi—is minimal in an age of electronic communication, while the Fifth Circuit has held that “once minimum contacts are established, the interests of the forum and the plaintiff justify even large burdens on the defendant.” *McFadin v. Gerber*, 587 F.3d 753, 764 (5th Cir. 2009). Accordingly, the exercise of personal jurisdiction with respect to all claims is both fair and reasonable, and comports with due process.

II. DEFENDANTS’ RULE 12(b)(6) MOTION SHOULD BE DENIED

Defendants’ Rule 12(b)(6) motion must be denied if, “constru[ing] the complaint in the light most favorable to the plaintiff,” Cypress can demonstrate that it is “entitled to relief under any set of facts or any possible theory that [it] could prove consistent with the allegations in the complaint.” *Equal Access for El Paso, Inc. v. Hawkins*, 562 F.3d 724, 726-27 (5th Cir. 2009) (quoting *Audler v. CBC Innovis Inc.*, 519 F.3d 239, 247 (5th Cir. 2008)).

Defendants argue that New Jersey law requires the Court to dismiss Cypress's tort claims under the "economic loss rule." Defs. Br. 12-17. But New Jersey law does not apply to *any* claims in this case, for two reasons. First, Mississippi courts will not honor a choice of law that bears no relation to the substance of the contract and has no other reasonable basis. Second, even if New Jersey law were to govern the contract claim, the choice of law provision does not apply to Cypress's tort claims. The provision only applies to the "Agreement." Because New Jersey law does not apply, Defendants have failed to establish a legal basis for their motion, and it should be denied for that reason alone.

Defendants also fail to show that New Jersey law requires dismissal of Cypress's tort claims. At bottom, Defendants argue that Plaintiffs have failed to plead the element of "duty" for each of the tort claims. Defendants are wrong: Plaintiffs show that (1) Defendants' duty to disclose the data falsification arose, at a minimum, because after the study was completed Defendants learned that they had made false statements about the integrity of Study S08-0179; (2) Defendants' duty to perform the study with reasonable care and skill arose because without such an exercise of care, injury to Cypress was particularly foreseeable to Cetero, and Cetero was in the best position to prevent the injury; and (3) Defendants' fiduciary duty arose because Cypress placed its trust and confidence in Cetero's expertise to conduct a clinical study. These duties arise by operation of law, and breach of these duties is actionable in tort.

A. New Jersey Law Does Not Govern The Claims In This Case

1. *The choice of law provision does not apply because no relationship existed between New Jersey and the parties or transaction*

A federal court sitting in diversity applies the conflict of law rules of the state in which the suit is brought. *See, e.g., Sorrels Steel Co. v. Great Sw. Corp.*, 906 F.2d 158, 167 (5th Cir. 1990). In the absence of contrary authority, Mississippi courts have followed the Restatement

(Second) of Conflicts of Laws (1971). *See id.*; *PIC Grp., Inc. v. LandCoast Insulation, Inc.*, 718 F. Supp. 2d 795, 799 (S.D. Miss. 2010) (analyzing whether to honor choice of law provision under Restatement). As relevant here, Section 187 of the Restatement provides that where “the chosen state has no substantial relationship to the parties or the transaction and there is no other reasonable basis for the parties choice,” the parties’ choice of law does not control. Restatement (Second) of Conflict of Laws § 187(2) (1971). To determine whether a “substantial relationship” exists, courts examine contacts with the state whose law is named in the contract. *See, e.g., Sorrels Steel Co.*, 906 F.2d at 168 (“[Florida] bears a reasonable relationship to the object of the contract because the Tampa Performing Arts Center is located in Florida, Sorrels delivered the steel to Florida, and GSW is located in Florida.”); *Bancorp Equip. Fin., Inc. v. Moak*, No. 3:05-cv-779-HTW-LRA, 2008 WL 2902341, at *2 (S.D. Miss. July 23, 2008) (“Minnesota law bears a reasonable relationship to the object of the contract because Firststar Bank, N.A., the company that originally leased the trucks to Moak, was located in Minnesota.”).

Defendants do not identify any contacts between the parties or events of this case and New Jersey, and none exist: No parties in this case are incorporated or located in New Jersey. No relevant events took place there. Defendants even aver that the contract “contained a New Jersey choice of law provision because New Jersey was a neutral state and New Jersey law was well developed with regard to pharmaceutical companies and their related issues given that many pharmaceutical companies are located in New Jersey.” Declaration of John Capicchioni ¶ 5 [dkt. no. 12-3]. In other words, Defendants argue that New Jersey is a neutral forum and bears no relation to these parties, their contract, or performance under the contract. Although the Restatement contemplates that parties with no relationship to a foreign state may have a reasonable basis for choosing foreign law “when contracting in countries whose legal systems

are strange to them as well as relatively immature,” Restatement (Second) of Conflict of Laws § 187, cmt. f. (1971), that circumstance plainly does not apply here. There is no reasonable basis for applying New Jersey law to the claims before this Court.

2. *The choice of law provision does not apply to tort claims*

Section 15.6 of the Study Agreement provides: “This Agreement shall be construed according to and governed by the laws of the State of New Jersey, without regard to principles of conflicts of law.” Assuming *arguendo* that Mississippi law permits the application of New Jersey law to *any* of Plaintiffs’ claims, the *scope* of the choice of law provision should be decided under Mississippi law. See *Finance One Pub. Co. v. Lehman Bros. Special Fin., Inc.*, 414 F.3d 325, 333 (2d Cir. 2005) (holding that court sitting in diversity applies law of forum state to “determine the scope of the contractual choice-of-law clause” (citation omitted)).

This Court should follow the “great majority” of cases⁵ holding that “the choice-of-law clause did not encompass tort claims” where “the clause spoke of ‘the contract’ or ‘the agreement,’ rather than the whole relationship resulting from the contract.” Symeon C. Symeonides, *Choice of Law in the American Courts in 2005: Nineteenth Annual Survey*, 53 Am. J. Comp. L. 559, 630 & n.459 (Summer 2005) (reporting results of 2005 survey and citing numerous cases). The relevant language here is narrow—the *only* object of the provision is “This Agreement”—and therefore the scope of the choice of law provision is narrow.⁶ Nothing

⁵ In *JGT, Inc. v. Ashbritt, Inc.*, No. 1:09cv380WJG-JMR, 2010 WL 1633530 (S.D. Miss. Apr. 21, 2010), a case involving a similarly worded choice-of-law clause specifying Florida law, the Court applied Florida law to the contract pursuant to that clause, but analyzed the tort claim separately under both Florida and Mississippi law “in the event that Mississippi law should apply to the tort claim.” See *id.* at *2-3.

⁶ See *Benchmark Elecs., Inc. v. J.M. Huber Corp.*, 343 F.3d 719, 726 (5th Cir. 2003) (holding that clause providing that “the ‘Agreement shall be governed by, and construed in accordance with, the internal laws of the State of New York’” was narrow and did not encompass tort claims); *Thompson & Wallace of Memphis, Inc. v. Falconwood Corp.*, 100 F.3d

in the text of the Agreement indicates that the parties intended that tort claims of any kind, and especially not *fraud* claims, should be governed by New Jersey law. In the absence of indications of contractual intent, the Court should not assume that the parties reached an agreement concerning tort claims. The provision is clear and unambiguous: assuming *arguendo* that Defendants could somehow show a substantial relationship to New Jersey, New Jersey law would govern a claim for breach of “*This Agreement*”—and nothing more.

B. Defendants Fail To Show That New Jersey Law Requires Dismissal Of Plaintiffs’ Tort Claims

1. *The economic loss doctrine applies only to product liability claims*

As a preliminary matter, the economic loss doctrine has no bearing on this case.⁷ The doctrine applies to product liability claims, and Cypress has not asserted any such claims. *See Dean v. Barrett Homes, Inc.*, 8 A.3d 766, 771 (N.J. 2010) (“The economic loss rule ... bars tort

429, 433 (5th Cir. 1996) (“Narrow choice-of-law provisions are to be construed narrowly.”); *Kreger v. General Steel Corp.*, No. 07-575, 2010 U.S. Dist. LEXIS 86043, at *37 (E.D. La. July 19, 2010) (holding that choice law of provision applying to “This agreement” did not encompass claims sounding in tort); *cf. Caton v. Leach Corp.*, 896 F.2d 939, 943 n.3 (5th Cir. 1990) (providing example of broad choice of law provision).

⁷ The “economic loss doctrine was first espoused” in *Seely v. White Motor Co.*, a decision of the California Supreme Court. *State Farm Mut. Auto. Ins. Co. v. Ford Motor Co.*, 736 So. 2d 384, 387 (Miss. App. 1999). In announcing the doctrine, the *Seely* court grounded it in the history of tort law. In the early 20th century, courts recognized that a manufacturer may be liable “in negligence to an ultimate consumer without privity of contract.” *Seely v. White Motor Co.*, 403 P.2d 145, 149 (Cal. 1965). The policy rationale for extending liability to manufacturers for personal injury resulting from use of products did not extend, however, to mere economic losses resulting from the use of products. *See id.* at 149-152; *State Farm*, 736 So. 2d at 387; *accord Alloway v. General Marine Indus., L.P.*, 695 A.2d 264 (N.J. 1997). Thus, the economic loss doctrine set an outer limit on liability for manufacturers who place products in the stream of commerce. Where products are *not* involved, foreseeability and duty set the boundaries of potential liability. But in “products-liability law, where there is a duty to the public generally, foreseeability is an inadequate brake.” *East River S.S. Corp. v. Transamerica Delaval, Inc.*, 476 U.S. 858, 874 (1986). Because Cypress does not allege strict liability or negligence based on a manufacturer’s defective product design or build, the economic loss rule is inapposite. Just as clearly, the doctrine has nothing whatever to do with fraud claims. *See Alloway*, 695 A.2d at 273-74 (observing that economic loss doctrine does not displace “common-law fraud” remedies).

remedies in strict liability or negligence when the only claim is for damage to the product itself.”). The Mississippi Supreme Court has not recognized the doctrine, and to the extent the doctrine has any force in Mississippi, it applies only in product liability cases. *See In re Chinese Manufactured Drywall Products Liability Litig.*, 680 F. Supp. 2d 780, 795 (E.D. La. 2010) (noting that Mississippi Supreme Court has not recognized economic loss doctrine); *Federal Ins. Co. v. General Elec. Co.*, No. 2:08cv156KS-MTP, 2009 WL 4728696, at *8 (S.D. Miss. Dec. 3, 2009) (“[T]he economic loss doctrine has not been extended beyond product liability cases to apply to tort claims involving a duty shaped by a contract.”).

Defendants’ actual argument is that Cypress failed to allege the element of “duty.” Cypress demonstrates below that it has alleged the element of duty—the only challenged element—for its fraudulent concealment, fraudulent misrepresentation, negligent misrepresentation, negligence, and breach of fiduciary duty claims. Even assuming *arguendo*, for the purposes of this section, that New Jersey law applies, Cypress has pleaded valid tort claims even under that state’s law.⁸

2. *Cypress sufficiently alleges fraud claims against Defendants*

The Complaint alleges that Defendants conducted a clinical study and delivered their final study report on October 24, 2008. *See* Compl. ¶¶ 18-27. The report certified that Cetero had complied with Good Laboratory Practices and Good Clinical Practices. *See, e.g., id.* ¶ 64. Although these statements were false, the Complaint does *not* allege that Defendants committed fraud by delivering the report. Rather, the Complaint alleges that months later, at least by June 2009, Defendants learned that their employees had falsified data and that, therefore, the

⁸ The only exception is the tortious breach of contract claim, which exists under Mississippi law, *see, e.g., David v. Flagstar Bank, FSB*, No. 5:09-CV-21-DCB, 2010 WL 716220, at *3 (S.D. Miss. Feb. 24, 2010), but not New Jersey law.

“integrity, quality, and reliability of Study S08-0179 were compromised.” *Id.* ¶ 66. Defendants knew and intended that Cypress would rely on the integrity of the S08-0179 Study. *See id.*

¶¶ 64, 69. But instead of warning Cypress that its reliance was misplaced, Defendants concealed the data falsification by their employees from Cypress for as long as possible. *See* Compl. ¶¶ 34, 40-46.

Between May and December 2009, Cetero had numerous communications with Cypress, but never disclosed that the S08-0179 Study was deficient and compromised. Compl. ¶ 34. Indeed, after the FDA commenced an inspection of Cetero’s Houston facility in May 2010, and in the face of repeated requests by Cypress for information, Defendants stonewalled Cypress and refused to disclose any information. *See id.* ¶¶ 39-46. By the time Defendants finally disclosed that the study had been fatally compromised due to their employees’ fraud, the damage was done: approximately one year had passed between the time that Cetero learned of the data falsification and the time they communicated its existence to Cypress. *See id.* ¶¶ 55-62. Defendants concealed these facts throughout 2009 and early 2010, culminating in their refusal of direct requests to reveal the content of an FDA inspection report observing that Cetero had falsified records “in at least 1900 instances over the period from April 15, 2005 to June 30, 2009.” *Id.* ¶ 50 (quoting FDA Form 483 issued to Cetero). Similarly, Cetero’s statements after June 2009 were materially misleading as they failed to disclose the existence of widespread data falsification.

Defendants’ sole asserted basis for dismissal is that the fraud claims are duplicative of the contract claim, *i.e.*, that Plaintiffs have alleged nothing more than ““fraudulent performance of the contract itself.”” Defs. Br. 17 (quoting *Unifoil Corp. v. Cheque Printers & Encoders Ltd.*,

622 F. Supp. 268, 271 (D.N.J. 1985)).⁹ The objection is groundless. Plaintiffs allege far more than willful breach; they allege intentional misrepresentation and concealment of facts, and the existence of a contract does not provide immunity for deliberate misrepresentations. *See Perth Amboy Iron Works, Inc. v. American Home Assur. Co.*, 543 A.2d 1020, 1029-30 (N.J. Super. Ct. App. Div. 1988) (holding that fraud claims should be tried where defendants misrepresented and concealed repairs to yacht), *aff'd*, 571 A.2d 294 (N.J. 1990).

To the extent that Cypress must allege that Cetero's fraud was something other than deliberate non-performance of contract terms, it has clearly done so. *After*¹⁰ the study had been completed and the report delivered, Defendants learned that the fraudulent conduct by their employees had compromised the integrity, quality and reliability of the study. Compl. ¶¶ 67, 73 (emphasis added). At that time, Defendants knew or should have known that they had made false statements on which Cypress relied, giving rise to a legal duty to correct the misrepresentations. *See Schillaci v. First Fid. Bank*, 709 A.D. 2d 1375, 1379 (N.J. Super. Ct. App. Div. 1998) (“[A] person who makes a false representation in good faith, believing at the time that it is true, is guilty of fraud, if on afterwards ascertaining the falsity of the representation, he fails to correct his statement.” (internal quotation marks and citation omitted)); *cf. Oran v. Stafford*, 226 F.3d 275, 286 (3d Cir. 2000) (Alito, J.) (in securities law, “[t]he duty to correct exists when a company makes a historical statement that, at the time made, the company

⁹ The New Jersey Appellate Division has criticized the *Unifoil* ruling as “inconsistent” with state statute and “state decisional law.” *Coastal Grp., Inc. v. Dryvit Sys., Inc.*, 643 A.2d 649, 652 (N.J. Super. Ct. App. Div. 1994); *see also Gleason v. Norwest Mortg., Inc.*, 243 F.3d 130, 144 (3d Cir. 2001) (“No New Jersey Supreme Court case holds that a fraud claim cannot be maintained if based on the same underlying facts as a contract claim.”). In any event, Cypress's fraud claims are not based on same underlying facts as the contract claim.

¹⁰ Defendants omit the word “after” from their quotation of paragraphs 67, 73, and 78 of the complaint. *See* Defs. Br. 16. The full paragraphs make clear that Cypress alleges the existence of a duty that arose “after” Cetero completed the acts contemplated under the contract.

believed to be true, but as revealed by subsequently discovered information actually was not.” (internal quotation marks and citation omitted)). The duty to disclose the data falsification arose not from the contract, but from the knowledge that their compliance statements were false. The existence of the Study Agreement does not release Defendants from this duty; it is only when the alleged deceit consists of nothing more than willful breach of contract that courts step in to prevent every breach of contract from becoming a fraud case. Cypress alleges far more than willful breach of contract. Defendants affirmatively concealed the data falsification beginning in 2009 and continued to do so even after repeated requests for information by Cypress. *See* Compl. ¶¶ 40-46. This constitutes concealment (Count One). Moreover, Defendants made numerous communications to Cypress that failed to disclose the data falsification. *See* Compl. ¶¶ 34, 40-46. These communications were materially misleading because they created the impression that Cypress could continue to rely on the S08-0170 Study, when in fact, it was worthless (Count Two).

3. *Cypress sufficiently alleges negligent misrepresentation*

The negligent misrepresentation claim, like the fraud claim, is not based on representations in the study report. Rather, it is based on Defendants’ discovery that their employees had falsified study data and their failure to communicate those vital facts, even though they knew that Cypress was relying on the purported validity of the study. *See* Compl. ¶ 78. New Jersey law permits a negligent misrepresentation claim where, as here, the claim is “based on the defendant’s silence or suppression of truth rather than on some affirmative misrepresentation.” *Highlands Ins. Co. v. Hobbs Grp., LLC*, 373 F.3d 347, 355 (3d Cir. 2004). A claim based on non-disclosure “is not limited to special relationship situations the required duty of disclosure may also arise in any situation called for by good faith and common

decency[.]” *Id.* Cetero should have known that the data falsification rendered its compliance statements false, and its failure to correct the misrepresentation was, at the very least, negligent.

Defendants proceed, without explanation, from a correct statement of New Jersey law—that no *negligence* claim lies absent duty owed independent of the contract—to the incorrect conclusion that the Plaintiffs’ negligent misrepresentation claim must be dismissed. *See* Defs. Br. 13-15 & n.10. Their citation to *South Broward Hospital District v. MedQuist Inc.*, 516 F. Supp. 2d 370 (D.N.J. 2007), does not supply the missing explanation or support the conclusion. In *MedQuist*, the plaintiff failed to plead a duty to disclose. *Id.* at 397. But Cypress has. *See* Compl. ¶ 78. Such duty exists here because injury to Cypress based on non-disclosure was not just foreseeable, but inevitable, and because basic fairness requires it. *See Snyder v. Am. Ass’n of Blood Banks*, 676 A.2d 1036, 1048 (N.J. 1996) (“The determination of the existence of a duty ultimately is a question of fairness and policy.”); *Carter Lincoln-Mercury, Inc. v. Emar Grp., Inc.*, 638 A.2d 1288, 1294 (N.J. 1994) (“[T]he more particular is the foreseeability that economic loss will be suffered by the plaintiff as a result of defendant’s negligence, the more just is it that liability be imposed and recovery allowed.”).

Cypress relied on Defendants to provide valid bioequivalence testing results for three active ingredients in support of Cypress’s application to the FDA for approval to market and distribute prescription drug products. *See* Compl. ¶¶ 18-30. Defendants knew that Cypress would rely on the S08-0179 study report and submit it to the FDA. *See id.* ¶ 28. Cypress accordingly placed its trust and confidence in Defendants, relied on their expertise in conducting clinical studies, and trusted that Defendants would promptly inform Cypress if they learned anything that would compromise the integrity of the study. *See id.* ¶¶ 90-93. Thus, Defendants “had particular knowledge or reason to know that others would be harmed by their negligent

conduct.” *Carter Lincoln-Mercury, Inc.*, 638 A.2d at 1294. And in fact, at least one district court has recognized a duty of care owed by a contract research organization where the risk of harm was considerably less foreseeable than in this case. *See Wawrzynek v. Statprobe, Inc.*, No. 05-1342, 2007 WL 3146792, at *14-15 (E.D. Pa. Oct. 25, 2007) (denying CRO’s motion for summary judgment on claim that CRO negligently provided clinical trial services to medical device manufacturer, causing plaintiff to suffer infection and spinal injury).

4. *Cypress sufficiently alleges negligence*

The negligence claim—unlike the fraudulent concealment, fraudulent misrepresentation, and negligent misrepresentation claims—is based on allegations that Defendants were negligent in performing the S08-0179 Study. *See* Compl. ¶¶ 82-88. Defendants simply assume, however, that because CRS had a contractual obligation to perform the study, they could not possibly have any liability arising from negligent conduct while performing the study. That is not the law. The operative New Jersey rule is that a plaintiff may assert a negligence claim arising from the performance of a contract, provided that the plaintiff sufficiently alleges “an independent duty imposed by law.” *Saltiel v. GSI Consultants, Inc.*, 788 A.2d 268, 280 (N.J. 2002); *accord First Trust Nat’l Ass’n v. First Nat’l Bank of Commerce*, 220 F.3d 331, 335 n.2 (5th Cir. 2000) (same). The *Saltiel* decision does not create a tort-liability-free zone for contracting parties (much less third parties), it simply states the unremarkable proposition that tort claims must be premised on tort duties. *See Highlands Ins. Co. v. Hobbs Grp., LLC*, 373 F.3d 347, 356 (3d Cir. 2004) (argument that negligence claim precluded by contract “misses the mark completely” where duty arises independent of contract). Plaintiffs have expressly alleged that CRS, BA Research, and PRACS “had a duty to exercise reasonable care and skill in the performance” of Study S08-0179,

Compl. ¶¶ 83-85,¹¹ and for the reasons stated above, New Jersey law recognizes that duty here, *see supra* Part II.B.3; *see also Carter Lincoln-Mercury, Inc.*, 638 A.2d at 1294 (citing *People Express Airlines v. Consolidated Rail*, 495 A.2d 107 (N.J. 1985)); *accord George B. Gilmore Co. v. Garrett*, 582 So. 2d 387, 391 (Miss. 1991) (“Accompanying every contract is a common law duty to perform with care, skill and reasonable experience, and a negligent failure to observe any of these conditions is a tort[.]” (internal quotation marks omitted)).

5. *Cypress sufficiently alleges breach of fiduciary duty*

Defendants make virtually no argument and cite no case specifically relating to the breach of fiduciary duty claim. *See* Defs. Br. 16 n.11. In any event, Cypress has stated a claim for breach of fiduciary duty by alleging that it reposed trust and confidence in Defendants and their expertise, insofar as Cypress relied on Defendants to protect the integrity of its new drug application to the FDA; that Defendants breached that trust by failing to inform Cypress that the integrity of the S08-0179 Study, and thus the application, had been destroyed; and that Cypress suffered damages as direct result of Defendants’ breach of that duty. *See* Compl. ¶¶ 89-97; *Vibra-Tech Eng’rs, Inc. v. Kavalek*, No. 08-2646-NLH, 2011 WL 111417, at *3 n.11 (D.N.J. Jan. 13, 2011) (“To prove a breach of fiduciary duty, the plaintiff must prove: (1) a fiduciary relationship existed between the parties, (2) a breach of the duty imposed by that relationship, and (3) harm to the plaintiff.”); Restatement (Second) of Torts § 874 cmt. a. (1979) (“A fiduciary relation exists between two persons when one of them is under a duty to act for or to give advice for the benefit of another upon matters within the scope of the relation.”). Accordingly, Cypress has pleaded each of the elements of its claim, and Defendants fail to show otherwise.

¹¹ Cypress also alleges that Defendants CRS, PRACS, and BA Research had a duty to exercise due care in the training and supervision of their employees, and that they breached that duty. *See* Compl. ¶¶ 86-87.

C. Defendants' Argument That The Study Agreement Precludes Recovery Of Punitive Damages Is Premature And Incorrect

Defendants argue that Cypress cannot recover punitive damages on its tort claims because the Study Agreement has a limitation provision that precludes punitive damages. *See* Defs. Br. 17-18. Defendants do not argue that Plaintiffs have “fail[ed] to state a claim upon which relief can be granted,” Fed. R. Civ. P. 12(b)(6), but instead prematurely and improperly move for a ruling on an affirmative defense to Plaintiffs’ claims. To the extent that any ruling could be made on the basis of the Study Agreement alone, Plaintiffs’ fraud and negligent misrepresentation claims unambiguously fall outside the scope of the limitation clause. The scope of the clause with respect to the remaining claims, however, is a question of fact to be determined at trial. Even as applied to the Study Agreement, the liability clause is invalid because it is unconscionable under Mississippi law.

For the reasons stated above, New Jersey law does not govern any of the claims in this case, and especially not the tort claims. *See supra* Part II.A. Mississippi law governs the analysis of the limitation clause for an additional reason: Even if another state’s law would otherwise be applied, “[w]here that law is contrary to the deeply ingrained and strongly felt public policy of [Mississippi, courts] may nevertheless apply and enforce [Mississippi’s] positive substantive law.” *Boardman v. United Services Auto. Ass’n*, 470 So.2d 1024, 1031 (Miss. 1985). Mississippi courts carefully scrutinize liability limitation provisions and do not enforce them if the terms are too one-sided. *Pitts v. Watkins*, 905 So. 2d 553, 556 (Miss. 2005) (“Clauses that limit liability are given *strict scrutiny* by this Court.” (emphasis added)). Because of Mississippi’s policy of giving strict scrutiny to limitation clauses, to the extent the Court examines the limitation clause at all—and it need not do so on a motion to dismiss—the Court should apply Mississippi law.

1. *The scope of the limitation clause raises questions of fact not suited for disposition on a motion to dismiss*

Any clause limiting liability must be expressed in clear and unmistakable language. *See, e.g., Turnbough v. Ladner*, 754 So. 2d 467, 469 (Miss. 1999) (exculpatory clauses “are subject to close judicial scrutiny and are not upheld unless the intention of the parties is expressed in clear and unmistakable language”). Courts will “not sanction broad, general ‘waiver of negligence’ provisions, and strictly construe them against the party asserting them as a defense.” *Id.* at 469. Here, the limitation clause is one-sided, vague, general, and broad, and should not be given any effect by the Court, especially at this stage in the litigation. The Study Agreement provides that “Section 12 states CETERO’s entire liability to [Cypress] with respect to the Services provided under this Agreement.” The term “Services,” in turn, is defined as “the Study described in the Protocol.” Study Agreement § 1.1. Thus, the Agreement does not make clear whether the parties intended to eliminate liability for certain claims, or certain acts.

However, no matter what the applicability of this clause to the contract, negligence, and breach of fiduciary claims, there is no reasonable construction that could limit Defendants’ liability for fraudulent concealment, fraudulent misrepresentation, and negligent misrepresentation. As set forth above, these claims are based on the fact that Defendants learned, *after* delivering the study report to Cypress, that their employees had falsified data in at least 1,900 instances over four years, putting Cypress’s new drug application to the FDA at risk (and ultimately resulting in rejection). *See supra* Part II.B.2-3.

2. *The limitation clause is substantively unconscionable*

In *Pitts v. Watkins*, the Mississippi Supreme Court held that a limitation on liability clause very similar to the provision in the Study Agreement was substantively unconscionable. *Id.* at 556. In that case, the clause limited the defendant’s liability for any wrongdoing to the

amount paid for the services, and further “release[d the defendant] from any and all additional liability” and “consequential damages.” *Id.* The Court held that the clause “place[d] an unreasonable restriction to collect compensatory damages” by restricting those damages to the payment obligation on the contract. *Id.* Substantive unconscionability is especially clear in this case because the limitation provision is one-sided, *i.e.*, it purports to limit Cetero’s damages, while Cypress’s damages are unlimited. *See Pitts*, 905 So. 2d at 556 (“This arbitration clause is clearly one-sided, oppressive, and therefore, substantively unconscionable.”); *Vicksburg Partners, L.P. v. Stephens*, 911 So. 2d 507, 523 (Miss. 2005) (contract that limited one party to recovery of \$50,000 or less without limiting damages for other party evinced “garden variety substantive unconscionability”), *overruled in part on other grounds*, *Covenant Health & Rehab. of Picayune, LP v. Estate of Moulds*, 14 So. 3d 695 (Miss. 2009). Even if New Jersey law applies—contrary to Mississippi public policy—the law of that State also holds that a limit on liability for intentional torts is void as a matter of public policy. *See Hojnowski v. Vans Skate Park*, 901 A.2d 381, 386 (N.J. 2006) (“It is well settled that to contract in advance to release tort liability resulting from intentional or reckless conduct violates public policy.”); *see also* Restatement (Second) of Contracts § 195(1) (1981) (“A term exempting a party from tort liability for harm caused intentionally or recklessly is unenforceable on grounds of public policy.”).

D. Hawthorn States A Claim

Hawthorn Pharmaceuticals, Inc. (“Hawthorn”) has sufficiently stated a claim in this case. As alleged in Plaintiffs’ Complaint, Hawthorn is a wholly-owned subsidiary of Cypress. Compl. ¶ 8. The Complaint alleges that “Cypress,” defined for the purposes of the Complaint as including both Hawthorn and its parent, is a Mississippi pharmaceutical company seeking to market new drugs for the treatment of cough and cold symptoms. *See* Compl., at 1 (preamble),

¶ 1, 7. Hawthorn is the subsidiary of Cypress that markets “branded” pharmaceutical products (as opposed to “generic” pharmaceutical products). It was foreseeable that Cypress would seek to market a branded pharmaceutical product, such as the one for which approval was being sought in this case, through its Hawthorn subsidiary, and that the Hawthorn subsidiary would be injured and damaged by Defendants’ tortious conduct. Accordingly, the motion to dismiss as to Hawthorn should be denied.

CONCLUSION

Plaintiffs relied on the expertise and experience of Defendants, and entrusted to them the conduct of an important clinical study. Defendants’ employees falsified scientific records while conducting that study, rendering the study worthless. Yet Defendants withheld this vital information from Plaintiffs for at least a year, causing injury and damages. Now Defendants seek to escape the consequences of their tortious actions, alleging that this Court has no jurisdiction over them, and/or that the Court should dismiss based on the law of a jurisdiction that has no connection to the parties or to the events relevant to this case. As shown above, these arguments do not pass muster. The motion to dismiss should be denied in its entirety.

DATED this the 3rd day of March, 2011

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, P. Ryan Beckett, do hereby certify that I have electronically filed the foregoing instrument with the Clerk of the Court using the ECF system which sent notification to the following ECF participants:

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SO CERTIFIED this the 3rd day of March, 2011.

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